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Michael P. Whitman

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

SMITH, PHILIP ROBERT

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/099,634
Filing Date: March 15, 2002
Appellant(s): WHITMAN ET AL.

Clifford Ulrich
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/12/2009 appealing from the Office action mailed 12/12/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,576,167	NOILES	3-1986
5,402,769	TSUJI	4-1995
6,099,464	SHIMIZU	8-2000
4,654,701	YABE	3-1987

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

[01] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

[02] Claims 1-2,7-9,11-12,14-16,19,40-43,48-51 are rejected under 35 USC 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769).

[03] With regard to claim 1: Noiles discloses:

[03a] a flexible shaft, comprising:

- a flexible, elongated outer sheath ("outer shaft tube 60," 13/4);
- at least one drive shaft ("flexible band 80," 8/45) disposed within the outer sheath;
- a coupling (comprising elements "234," "235," "30," "78," "264," "260," shown in Figure 11) connected to an endoscope of the outer sheath.

[03b] Noiles does not disclose:

- a moisture sensor disposed within the coupling configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.

[03c] Tsuji discloses a “humidity sensor 22” and a “leakage detecting circuit 24” (4/49) which work in tandem to warn of leakage within an outer shaft of an insertable medical instrument. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a moisture sensor such as that disclosed by Tsuji in the coupling disclosed by Noiles. A skilled artisan would be motivated to do so in order to enhance reusability by enabling sterilization, a necessary precondition of reusability in surgical instruments.

[04] With regard to claim 2: the outer sheath disclosed by Noiles is autoclavable.

[05] With regard to claim 7: the coupling disclosed by Noiles is configured to detachably couple to a surgical attachment (“anvil assembly 220,” 13/40).

[06] With regard to claims 8-9: Noiles discloses that the detachable coupling includes a flexible strip locking mechanism (“retention ring 260,” 12/59) for detachably coupling to the outer sheath.

[07] With regard to claim 50: Tsuji discloses that the moisture sensor communicates the sensor data via a data transfer cable (4/48-68).

[08] With regard to claim 51: Tsuji discloses that the moisture sensor comprises a board element (“insulating substrate 51,” 5/67), a first lead, and a second lead (“comb-like electrode patterns 52 and 53,” 5/66-6/13), the first lead and the second lead printed on the board element, the electrical resistance between the first lead and the second lead varying in accordance with an amount of moisture present (“humidity-sensitive resistor coating 54,” 6/4).

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[09] With regard to claim 11: As noted above, Noiles in view of Tsuji discloses

[09a] a flexible shaft, comprising:

- a flexible, elongated outer sheath (“outer shaft tube 60,” 13/4);
- at least one flexible drive shaft (“flexible band 80,” 8/45) disposed within the outer sheath;
- a coupling (comprising elements “234,” “235,” “30,” “78,” “264,” “260,” shown in Figure 11) connected to a distal end of the outer sheath configured to couple to a surgical attachment (“anvil assembly 220,” 13/40); and
- a moisture sensor (“humidity sensor 22” & “leakage detecting circuit 24,” 4/49) disposed within the coupling configured to communicate sensor data corresponding to the presence of moisture; and

[10] With regard to claim 12: as noted above, the outer sheath is autoclavable.

[11] With regard to claims 14-16: as noted above, the coupling disclosed by Noiles in view of Tsuji includes a flexible strip locking mechanism (comprising at least “260,” as noted above) so that the coupling attaches and detaches to the outer sheath.

[12] With regard to claim 19: as noted above, Noiles in view of Tsuji discloses a moisture sensor configured to detect moisture. At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the moisture sensor be disposed in the coupling disclosed by Noiles. A skilled artisan would be motivated to do so in order to provide leakage detection capability in a sterilizable portion of a surgical instrument.

[13] With regard to claim 40: as noted above, Noiles in view of Tsuji discloses a shaft, comprising an elongated outer sheath; at least one drive shaft disposed within the outer sheath; and a moisture

sensor disposed a coupling connected to an end within the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.

[14] With regard to claims 41-42: the shaft disclosed by Noiles is rigid and articulable.

[15] With regard to claim 43: as noted above, the outer sheath is autoclavable.

[16] With regard to claims 48-49: as noted above, Noiles in view of Tsuji discloses a coupling detachably connected to an end of the outer sheath, the coupling being configured to detachably couple to a surgical attachment, the detachable coupling including a locking mechanism ("260," as noted above) for detachably coupling to the outer sheath.

Additional Claim Rejections - 35 USC § 103

[17] Claims 37-39 are rejected under 35 USC 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769).

[18] With regard to claim 37:

[18a] As noted above, Noiles in view of Tsuji discloses:

- a flexible shaft, comprising: a flexible, elongated outer sheath; at least one drive shaft disposed within the outer sheath;
- a coupling detachably connected to an end of the outer sheath (comprising elements "234," "235," "30," "78," "264," "260," as noted above), the coupling being configured to detachably couple to a surgical attachment ("220," as noted above); and
- a moisture sensor disposed within the coupling configured to detect moisture within the outer sheath.

[18b] Noiles further discloses

- wherein the coupling includes a connection mechanism configured to detachably

couple to the surgical attachment;

- that the coupling includes an engagement shaft including grooves (“threaded distal end portion 234 of rod 30,” 13/46);
- a clip (“proximal end 243,” 12/65) having flanges (“outwardly projecting lugs 245,” 13/1);
- the flanges of the clip configured to engage in longitudinal slits (“L-shaped slots 264,” 13/31) of a hollow engagement member;
- the clip configured to receive and secure the engagement shaft in the hollow engagement member, and to frictionally engage with the grooves of the engagement shaft.

[18c] Noiles in view of Tsuji does not disclose

- that the clip having flanges is included in the coupling (clip “243” having flanges “245” is instead included in the surgical attachment “220.”);
- that the longitudinal slits are included in a hollow engagement member of the surgical attachment (longitudinal slits “264” are included in a hollow engagement member of the coupling).

[18d] At the time of the invention, it would have been an obvious variation to reverse the disposition of the longitudinal slits with respect to the flanges, such that the longitudinal slits are included in the surgical attachment instead of the coupling, and vice-versa with respect to the clip having flanges. It is clear to a skilled artisan that so long as the flange engages the longitudinal slits, the “anvil assembly 220” may be reliably “mounted on the distal end of shaft assembly 16” such that “the apparatus is ready for use” (13/59-61).

Additional Claim Rejections - 35 USC § 103

- [19] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [20] Claims 3,13,44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769) and in further view of Shimizu (6,099,464).
- [21] With regard to claims 3,13,44: Noiles in view of Tsuji discloses an outer sheath, as noted above. Noiles in view of Tsuji does not disclose that the outer sheath includes a fluoropolymer/silicone material.
- [22] Shimizu discloses “an outer sheath 9a of Teflon (trade name) such as PTFE (polytetrafluoroethylene) or TFE (tetrafluoroethylene)” (6/40-45). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a fluoropolymer material in the outer sheath disclosed by Noiles in view of Tsuji. A skilled artisan would be motivated to do so in order to construct the outer sheath of a smooth and biologically inert material. Fluoropolymer has these well-known properties.

Additional Claim Rejections - 35 USC § 103

- [23] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [24] Claims 4-6,20-21,45-47 are rejected under 35 USC 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769) and in further view of Yabe (4,654,701).
- [25] With regard to claims 4,20,45:
- [25a] Noiles in view of Tsuji discloses:
- a coupling (comprising elements “234,” “235,” “30,” “78,” “264,” “260,” as noted above)

connected to an end of an outer sheath.

[25b] Noiles in view of Tsuji does not disclose:

- a memory unit disposed in the coupling.

[25c] Yabe discloses

- a “RAM 22” in which “examination serial number (data D1), patient's name (data D2), patient's number (data D3) and examination date (data D4) are keyed in or read out of a card in [an] input device 16 and stored in respective memory areas” (2/23-45).

[25d] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to store data including at least one of serial number data, identification data and usage data in a random access memory in instrument disclosed by Noiles in view of Tsuji. A skilled artisan would be motivated to do so in order to coordinate surgical data with patient information.

[26] With regard to claim 5,21,46: as noted above, Yabe discloses that the memory unit stores data including at least one of serial number data, identification data and usage data.

[27] With regard to claim 6,47: Yabe discloses a data transfer cable disposed within the outer sheath, wherein the memory unit is logically and electrically connected to a data transfer cable.

(10) Response to Argument.

Applicant contends that in Noiles, “there is no interior volume that is sealed from the external environment” and that “no portion within what the Final Office Action considers to be a coupling has any sealed interior portion.” Applicant concludes that “there is no apparent motivation or reason why one of ordinary skill in the art would

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include a moisture sensor within the portion of the Noiles device considered by the Examiner to constitute a coupling.”

As noted in the previous Office action, there is no recitation in the claim of a sealed interior volume. Therefore, Noiles need not disclose a sealed interior volume to support a rejection. Nevertheless, Noiles does disclose a “hollow extension tube 78.”

With respect to the argument that a skilled artisan would have no motivation to combine a humidity sensor with an instrument lacking a sealed interior volume, it is first reiterated that the claim does not require a sealed interior volume, and that Noiles' disclosure does in fact contain hollow elements. Secondly, it is maintained that even if it is agreed that Noiles fails to disclose a sealed interior volume, there still is a motivation for a skilled artisan to combine a humidity sensor with the instrument. For example, a humidity sensor may be used to indicate use of a sterilizable instrument having no sealed interior volume. If the instrument of Noiles is not sealed, as Applicant avers, then a skilled artisan would still be motivated to provide a humidity sensor such as that disclosed by Tsuji, and use it to register exposure to a surgical environment. It is common in the field of surgical instruments to detect when an instrument has been exposed to a surgical environment so as to ensure that the instrument is sterilized prior to re-use.

Applicant further contends that “there is no indication whatsoever that the presence of moisture within any portion of the device of Noiles, which does not include any internal electronics, would make the device any less sterilizable.” However, internal electronics are not recited in the claim; and secondly, a skilled artisan would be

motivated to provide a humidity sensor to register the need for sterilization (as noted above) regardless of the presence of internal electronics, or lack thereof.

Furthermore, under the rule of *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, a motivation for a skilled artisan (such as the one noted above) need not be explicit. The Court states that “a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id* at 401. It is perfectly clear that Noiles discloses a surgical instrument comprising a flexible elongated sheath having a drive shaft within and a coupling connected to the end; and that Tsuji discloses a moisture sensor for use with surgical instruments. Therefore, the elements are familiar. Applicant makes no argument to the contrary. It is well within the expertise of a skilled artisan to construct the two in a single device, especially given the lack of structural specificity in the claim as to the interrelatedness of the various recited elements. The claim positively recites only that the sensor is “within” the coupling, which is at “an end” of the device. Surely it is a known method to place a humidity sensor “within” a surgical device and at “an end.” Tsuji demonstrates as much. Lastly, the result is predictable: the device would sense moisture “within” the coupling.

In summary, there is motivation to a skilled artisan to place a humidity sensor within the coupling disclosed by Noiles. Furthermore, there are no significant structural limitations in the claim which would preclude a finding that the two were combined according to a “known method.” A skilled artisan could simply implant the sensor, as taught by Tsuji, for the purpose of sensing moisture.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Philip R Smith/

Examiner, Art Unit 3739

Conferees:

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739

/Tom Hughes/

TQAS, TC 3700